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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,707	04/20/2001	Angela M.I. Lam	16303-008110	2773

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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 08/27/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,707

Applicant(s)

LAM ET AL.

Examiner

Dave Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☒ Other: *detailed action*.

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Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-63, and 68, drawn to a nucleic acid-lipid particle composition of claim 1, and a nucleic acid delivery method of employing the composition, classifiable in class 435, subclasses 320.1, 325, 455, 458, and class 514, subclass 44.

Group II. Claims 64-67, drawn to a method for inducing Hii fase structure in a lipid bilayer comprising the use of an endosomal membrane destabilizer, classifiable in class 424, subclass 450.

The inventions are distinct, each from the other because of the following reasons:

Group I, and Groups II are distinct because each group is directed to a distinct goal and comprises a materially distinct step. A search of Group II claims does not necessarily overlap with that of Group I claims, thereby generating an undue burden on the examiner.

Should Group I be elected, claims 5-7 are generic to a plurality of disclosed patentably distinct species comprising:

- 0.1 mM to about 100 mM;
- 1 mM to about 20 mM; and
- less than about 150 mM

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as listed above and cited in the claims, even though this requirement is traversed.

Should Group I be elected, claims 8 and 39 is generic to a plurality of disclosed patentably distinct species comprising:

A specifically named lipid as listed in the claims

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as listed above and cited in the claims, even though this requirement is traversed.

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Should Group I be elected, claims 10 and 41 are generic to a plurality of disclosed patentably distinct species of a specifically named noncationic lipid as listed in the claims

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as listed in the claims, even though this requirement is traversed.

Should Group I be elected, claims 13 and 44, together with claims 17, 18, 48, 49 are generic to a plurality of disclosed patentably distinct species of a specifically named hydrophilic polymer or a specifically named combination thereof as listed in the claims.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as listed in the claims, even though this requirement is traversed.

Should Group I be elected, claims 15 and 46 are generic to a plurality of disclosed patentably distinct species of a specifically named polycationic moiety as listed in the claims.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as listed in the claims, even though this requirement is traversed.

Should Group I be elected, claims 16 and 47 are generic to a plurality of disclosed patentably distinct species of a specifically named lipid moiety as listed in the claims.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as listed in the claims, even though this requirement is traversed.

Should Group I be elected, and should PEG be elected, claims 20 and 51 are generic to a plurality of disclosed patentably distinct species of a specifically named A as listed in claim 23, 26, **and** a specifically named species of Y as listed in claim 23, 25, 26, **and** a specifically named species of X as listed in claim 21



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or 52, and a specifically named Z as listed in claim 22 or 53.

Should Group I be elected, and should PEG be elected, claim 27 or 59 is generic to a plurality of disclosed patentably distinct species of a specifically named PEG-ceramide or PEG-phosphatidylethanolamine.


Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as listed in the claims, even though this requirement is traversed.

Should Group I be elected, claims 32 and 63 are generic to a plurality of disclosed patentably distinct species of a specifically named nucleic acid as listed in the claims

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as listed in the claims, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, and/or because of the patentably distinct species as listed above, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.



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Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is **(703) 305-3388**.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Clark*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
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DAVE T. NGUYEN
PRIMARY EXAMINER